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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,039	07/16/2003	Arun Srivastava	44141-034RI	8203

7590

04/30/2004

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,039

Applicant(s)

SRIVASTAVA, ARUN

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 16-23 and 26-30 is/are rejected.
- 7) ☒ Claim(s) 24 and 25 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/16/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/16/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Notice To Comply.

DETAILED ACTION

Non-Final Rejection

Claims 16-30 are pending.

Cancellation of claims 1-15 and the addition of claims 16-30 in paper filed on 7/16/03 is acknowledged.

The terminal disclaimer filed on 7/13/03 to overcome a double patenting rejection based on US Patent 5,252,479 is acknowledged and entered.

The statement in amendment filed on 7/13/03: "A Request for Reexamination of the '834 patent was filed on February 10, 2003, and was assigned Reexamination Application No. 90/006,542. The Request was denied on the ground that the prior art references cited in the Request do not raise any substantial new question of patentability. A copy of the Decision on the Request for Reexamination is also enclosed", is acknowledged. However, the examiner cannot locate the formal copy of the Decision. As a courtesy to the examiner, the examiner requests another formal copy of the Decision.

The statement in amendment filed on 7/13/03: "A civil proceeding captioned "Avigen, Inc. v. Research Corporation Technologies, Inc.", Case No. C02 0880, United States District Court for the Northern District of California, which is now dismissed. A copy of the Summons and a copy of the Dismissal Order of this civil action are enclosed", is acknowledged. However, the examiner cannot locate the formal copy of the

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Summons and the formal copy of the Dismissal Order. As a courtesy to the examiner, the examiner requests another formal copy of the Summons and Dismissal Order.

It is noted that applicants checked item 4 (OFFER TO SURRENDER THE ORIGINAL LETTERS PATENT IN ACCORDANCE WITH 37 CFR 1.178) in reissue application transmittal filed 7/16/03. However, the examiner cannot locate the formal copy of the offer to surrender the patent in accordance with 37 CFR 1.178. As a courtesy to the examiner, the examiner requests a formal copy of the offer to surrender the original letter patent in accordance with 37 CFR 1.1.78.

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Specification

The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definition for nucleotide sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements for Patent Applications Containing Nucleotide Sequence Disclosures.

A sequence is listed in the specification (Figure 2A), but is not listed in the CRF.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 17, 18, 19, 20, 22, 26, 27, 28, 29, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Shenk et al., (US 5,436,146).

Shenk teaches a rAAV vector comprising only terminal AAV sequences and any foreign DNA sequence operably linked to a promoter (column 5, line 67- column 6, line 3 and column 9, line 20- column 10, lines 46). Shenk teaches that the rAAV vector retains only terminal AAV sequences necessary for integration, excision, replication, and packaging comprising less than about 195 of the AAV terminus (column 9, lines 31-34). Shenk teaches using psub201, which comprises AAV-2 DNA (columns 10, 14, and 15). Shenk teaches using 191 bp segments from the termini of sub201 (column 15). Thus, Shenk anticipates using the terminal repeats of AAV-2 in the rAAV vector.

In addition, the 191 bp segments from the termini of sub201 would comprise the claimed sequences in claim 17 (SEQ ID NO: 1, AAV-2 ITR) and claim 18 (nucleotides 1 to 125 of SEQ ID NO: 1, AAV-2 ITR) because the applicants also used psub201 to obtain the AAV-2 ITRs (See column 5, lines 36-37 and columns 14-15 of the instant specification).

Furthermore, Shenk teaches that the DNA sequence used in the rAAV vector can be a gene selected from luciferase, thymidine kinase and neomycin phospho-transferase (column 9, lines 47-62). Shenk teaches using a tissue specific promoter in the vector (column 9, line 63-column 10, line 46). Shenk teaches producing helper free stocks of rAAV using cells (column 5, lines 55-66). Shenk teaches a host cell comprising rAAV virus (column 27, lines 30-65). Shenk teaches that an AAV vector has been used in gene transfer to progenitor cells (column 4, lines 59-61).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shenk et al., (US 5,436,146) taken with Kim et al., (Cell, 42:129-138, 1985).

Shenk teaches a rAAV vector comprising only terminal AAV sequences and any foreign DNA sequence operably linked to a promoter (column 5, line 67- column 6, line

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3 and column 9, line 20- column 10, lines 46). Shenk teaches that the AAV vector can be used to efficiently transduce foreign genes into host cells (abstract). Shenk teaches that the rAAV vector retains only terminal AAV sequences necessary for integration, excision, replication, and packaging comprising less than about 195 of the AAV terminus (column 9, lines 31-34). Shenk teaches using psub201, which comprises AAV-2 DNA (columns 10 and 14). Thus, Shenk teaches using the terminal repeats of AAV-2 in the rAAV vector. Shenk teaches using a tissue specific promoter in the vector (column 9, line 63-column 10, line 46). However, Shenk does not specifically teach using the heterologous gene encoding an antisense RNA in the rAAV vector.

However, at the time the invention was made, Kim teaches reducing thymidine kinase activity in mouse cells in vitro using anti-sense thymidine kinase gene (pages 129 and 130).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Shenk taken with Kim to use the heterologous gene encoding an anti-sense RNA in the rAAV vector. One of ordinary skill in the art would have been motivated to use a heterologous gene encoding an anti-sense RNA in the rAAV vector because a gene encoding an anti-sense can be used to inhibit thymidine kinase in mouse cells in vitro. In addition, one of ordinary skill in the art would have been motivated to use the AAV-2 vector to delivery the anti-sense RNA to a host cell because Shenk teaches that the AAV vector can efficiently transduce host cells.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shenk et al., (US 5,436,146) taken with Berg et al., (US 5,326,700).

Shenk teaches a rAAV vector comprising only terminal AAV sequences and any foreign DNA sequence operably linked to a promoter (column 5, line 67- column 6, line 3 and column 9, line 20- column 10, lines 46). Shenk teaches that the rAAV vector retains only terminal AAV sequences necessary for integration, excision, replication, and packaging comprising less than about 195 of the AAV terminus (column 9, lines 31-34). Shenk teaches using psub201, which comprises AAV-2 DNA (columns 10 and 14). Thus, Shenk teaches using the terminal repeats of AAV-2 in the rAAV vector. Shenk teaches using a tissue specific promoter in the vector (column 9, line 63-column 10, line 46). However, Shenk does not specifically teach using the heterologous gene encoding P-glycoprotein in the rAAV vector.

However, at the time the invention was made, Berg teaches introducing a gene encoding a P-glycoprotein into a cell line and using it as an amplifiable marker (column 10, lines 13-27).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Shenk taken with Berg to use the heterologous gene encoding P-glycoprotein in the rAAV vector. One of ordinary skill in the art would have been motivated to use a heterologous gene encoding P-glycoprotein in the rAAV vector because a gene encoding a P-glycoprotein can be used as a marker in gene transfer and Shenk teaches that any foreign DNA sequence can be used in the vector.

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Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Conclusion

Claims 24 and 25 are free of the prior art of record.

Claims 24 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,261,834 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

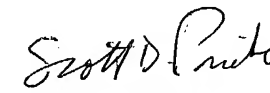
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER